REMARKS

Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, and 105 are pending. No new matter is added by this Response. Applicant respectfully notes that claim 63 is canceled, and Claims 76 and 90 are pending. Clarification is requested as to these claims.

I. SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENTS

Applicant respectfully requests Examiner Graffeo to sign and return the Forms PTO-1449 submitted with: (1) the Supplemental IDS filed via certificate of mailing on March 26, 2001; (2) the Second Supplemental IDS filed via certificate of mailing on December 21, 2001; and (3) the Third Supplemental IDS filed via certificate of mailing on March 8, 2002. Copies of these Supplemental IDS's and the corresponding PTO-stamped postcards are attached for the Examiner's consideration.

A Twelfth Supplemental Information Disclosure Statement and Notification of Copending Commonly Assigned Related Application is also being filed concurrently herewith.

II. RESTRICTION REQUIREMENTS

According to Applicant, the elected species are: (1) durum wheat as a plasticizable matrix material and (2) a probiotic neutraceutical component as an encapsulant. Applicant notes that the election of species requirement directed to the rate-controlling agent (hydrophobic component/fat) was withdrawn in the Office Action dated March 17, 2003. As to the additional matrix material, Applicant elected starch as the additional matrix material in Claim 79. As to the encapsulant form, Applicant elected the liquid encapsulant of Claim 93.

III. REJECTION UNDER 35 U.S.C. 112, FIRST PARAGRAPH

Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, and 105 were rejected under 35 U.S.C. 112, first paragraph, as assertedly failing to comply with the written description requirement. This rejection is respectfully traversed.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See MPEP 2163. As noted by the Examiner, for each claim drawn to a genus, the written description requirement may be satisfied for a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. What constitutes a representative number is an inverse function of the skill and knowledge in the art, something which the Examiner has not set forth in the Office Action.

The patent specificaiton contains sufficient detail to show Applicant was in possession of the claimed encapsulant genus. First, Applicant respectfully submits that the food art is not an unpredictable art on the same level as, for example, molecular biology arts. Second, the present application has 9 examples. Example 1 is directed to a pharmaceutical encapsulant (acetylcysteine). Example 2 is directed to a heat sensitive vitamin encapsulant (ascorbic acid). Example 3 is directed to a fat soluble encapsulant (salicylic acid). Examples 4-8 and Comparative Example 2 are directed to the encapsulation of ascorbic acid in various matrices using various extrusion conditions. Example 9 is directed to various matrix materials. Thus, at least three representative species of encapsulants and several types of matrices are shown by reduction to practice.

Moreover, one of ordinary skill in the food art would readily understand that the disclosure of the examples with different matrices and different extrusion conditions would apply to other species of encapsulants such as probiotics. Thus, the fact that the term probiotics is recited once in the specification is not pertinent. In view of the entire specification and the Examples which clearly show reduction to practice, one of ordinary skill in the art would understand that Applicant was in possession of the claimed generic encapsulant, including the species probiotics. Furthermore, the species probiotics is a well-known term to those skilled in the art as evidenced by the dictionary definition cited by the Examiner. The claims satisfy the written description requirement of 35 U.S.C. 112, first paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. REJECTION UNDER 35 U.S.C. 103(a)

Claim 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, and 105 were rejected under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 4,187,321 (Mutai et al.). This rejection is respectfully traversed.

Mutai et al. discloses foods and drinks containing bifidobacteria prepared by growing, in a milk medium under aerobic conditions, a mixture of bifidobacteria containing a mutant strain of oxygen-resistant Bifidobacterium and a strain of anaerobic Bifidobacterium (Abstract). The Examiner cites Example 3 for disclosing starch and col. 2, lines 35-43 for disclosing fat. Example 3 discloses that freeze dried cells were mixed with a 20-fold volume of dried starch and tabletted. Col. 2, lines 35-43 discloses that the media for cultivating the bacteria may be whole milk.

The citation of Mutai et al. to reject the claims is improper. The Examiner has reconstructed the present invention by citing a reference that assertedly contains the

elected species (probiotic; starch; fat [sic]) without considering the claimed invention as a whole or how the elected species interrelate. According to the elected species of the present invention, an encapsulated product comprises a probiotic encapsulant and a durum wheat **plasticized** mass or matrix material.

Mutai et al. does not teach or suggest an encapsulated product comprising discrete, solid particles wherein each particle comprises an encapsulant dispersed throughout a plasticized mass or plasticized matrix material, as recited in independent Claims 21, 52, and 83. There is no teaching or suggestion that the "dried starch" of Example 3 of Mutai et al. is a plasticized material.

As demonstrated by Examples 4 to 8 and Comparative Example 2 of the present invention, pure starch or non-plasticized starch such as the dried starch of Example 3 of Mutai et al. does not present a sufficient matrix for encapsulation, because the time to release 100% of the encapsulant is too short. In addition, Mutai et al. does not teach or suggest a plasticized mass or matrix which comprises durum wheat or semolina, wheat flour, wheat gluten, soy protein, hydrocolloids, casein, or gelatin. See Claims 42, 52, 69, and 83-84.

Even if the milk component upon drying provides a plasticized matrix material, there is no teaching or suggestion to employ it in an amount as claimed. There is simply no teaching or suggestion that the milk component provides a sufficient matrix for encapsulation which delays release of 100% of the encapsulant. In Example 3, as indicated by the Examiner, the 20 fold amount of starch leaves only 5% for the dried milk/probiotic component. It is not seen why one skilled in the art would be motivated to increase the amount of milk to at least about 40% by weight of the final product in an attempt to reduce the release rate of bacteria.

Mutai et al. also does not teach or suggest at least one component for controlling the rate of release of the encapsulant, as recited in independent Claims 21 and 52. There is absolutely no recognition or appreciation that the whole milk *cultivating media* for bacteria would also control the rate of release of the disclosed bacteria, or any kind of encapsulant, dispersed throughout a plasticized mass or matrix material. Mutai et al. also does not teach or suggest that an encapsulant and plasticized matrix material form an at least substantially homogeneous mixture, as recited in independent Claims 21, 52, and 83. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed encapsulated products in view of the teachings of Mutai et al. Reconsideration and withdrawal of the rejection are respectfully requested.

V. CONCLUSION

In light of the foregoing remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

Any shortages in fees should be charged to, or any overpayment in fees should be credited to, Deposit Account No. 501032 (Docket No. BVL-102A).

Respectfully submitted,

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Attachments:

Supplemental IDS filed via certificate of mailing on March 26, 2001 and stamped PTO-postcard;

Second Supplemental IDS filed via certificate of mailing on December 21, 2001 and stamped PTO-postcard; and

Third Supplemental IDS filed via certificate of mailing on March 8, 2002 and stamped PTO-postcard.

CERTIFICATE OF MAILING

I hereby certify that this correspondence dated 3/7/06 is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 3/7/06.

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